

July 28, 2017

Donald Rucker, MD
National Coordinator for Health IT
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

RE: Comments on the Proposed Interoperability Standards Measurement Framework

Dear Dr. Rucker:

The Strategic Health Information Exchange Collaborative (SHIEC) appreciates the opportunity to provide comments to the Office of the National Coordinator for Health Information Technology (ONC) regarding the ONC Proposed Interoperability Standards Measurement Framework based on our expertise with interoperable information exchange. We also invite the ONC to reach out to SHIEC as a trusted resource on this topic as this is critical to advancing effective health information exchange. SHIEC shares in the common goal of achieving interoperable health information exchange nationwide which ultimately supports effective care delivery and quality outcomes as well as provide the infrastructure to support *all* providers, consumers and patients.

The Strategic Health Information Exchange Collaborative (SHIEC) is the national trade association of health information exchanges (HIEs). Its 54 HIE member organizations manage and provide secure digital exchange of health data for hospitals, healthcare providers and other participants approaching more than seventy percent (70%) of the U.S. patient population. As the unbiased, data trustees in their communities; SHIEC member organizations serve a critical role through information exchange with advancing effective, efficient healthcare delivery to improve health on a local, regional and national level. SHIEC's membership expands beyond HIE organization to include 29 Strategic Business and Technology members and 4 Associate HIE members.

SHIEC supports ONC's role with advancing the adoption, deployment and utilization of interoperable systems, data exchange and standards across the nation. We recognize that Congress has mandated that the ONC establish metrics to determine if interoperability is achieved in the use of systems and data exchange. We agree with the ONC that a multi-prong

strategy is the best approach. In addition, we recognize the complexity and challenges in achieving this goal due to the current state of interoperability, the lack of uniform standards and, in some instances, the lack of any established standards. Below you will find the ten (10) questions on the *Proposed Interoperability Standards Measurement Framework* with SHIEC's response. SHIEC will gladly continue to share our insights and experience with the ONC to support this important effort.

- 1. Is a voluntary, industry-based measure reporting system the best means to implement this framework? What barriers might exist to a voluntary, industry-based measure reporting system, and what mechanisms or approaches could be considered to maximize this system's value to stakeholders?
  - It is possible that a voluntary reporting process may not produce a broad enough dataset for ONC to establish definitive patterns of use and utilization. That said, the reporting of this type and depth of data may well be beyond the capacity of the identified stakeholders. Potential barriers will be the cost of obtaining and tracking the data, the lack of a standard data collection tool built into each system and software application for reporting. To begin this process, it would most likely be a manual process and effort which most likely require additional manpower and resources. In addition, such reporting requirements may necessitate the addition of new processes and additional operating costs. Smaller organizations will probably opt-out of a voluntary reporting process due to their significant barriers, thereby limiting the total value of the data collected and its usefulness for the purpose of informing future standard needs and revisions.
- 2. What other alternative mechanisms to reporting on the measurement framework should be considered (for example, ONC partnering with industry on an annual survey)?
  - Utilizing existing reporting tools and data collection process such as those used by ONC for their annual Interoperability Standards Advisory is an excellent first step and provides the opportunity for the industry to offer suggestions and recommendations. Leveraging relationships with industry organizations such as SHIEC, HIMSS, CHIME, Standard Development organizations, the EHR Vendor Association, and many other professional associations and similar organizations will assist to inform the data gathering and reporting processes.

3. Does the proposed measurement framework include the correct set of objectives, goals, and measurement areas to inform progress on whether the technical requirements are in place to support interoperability?

The current EHR certification processes and requirements provide a guide for the EHR vendor community related to identification of the specific standards that should be included in CEHRT. One issue related to the current standards requirement is that there are options when more than one standard may be allowed to meet the certification criteria which inadvertently create interoperability incompatibilities between two different vendor's CEHRT. Identifying those choices for removal in future certification criteria might be a welcomed outcome of this measurement process.

A more difficult task would be to understand the impact of the requirement and utilization of specific standards on care processes such as coordination of care, transitions of care (acute to non-acute), chronic care management, referral processes, patient access and management of their medical information, drug therapy management, and/or abuse, as well as many others.

ONC also may evaluate options where SHIEC member organizations could support this effort leveraging their experience and knowledge of deployment and management of interoperable systems and connection of disparate systems.

4. What, if any gaps, exist in the proposed measurement framework?

Gathering the volume by standard may be more difficult to determine than which standards are in use or within the EHR development lifecycle. EHRs may not currently gather this level of information and would require additional features and functionality to be written into the application to provide the required level of internal reporting. If this is not automated, reporting methods would be a manual effort, most likely accomplished via a sampling methodology.

Customization of the standards is mentioned in Objective 2's measure areas. Since the term "customization" is not defined, it's difficult to understand what would be measured or how. One area around current interoperability issues is the "modification" of certain transition sets that require a level of "customization" during each implementation and installation of an EHR application/platform. This, in turn, creates opportunities for barriers to emerge for the advancement of interoperability and integration.

As mentioned above, one gap is how to measure the impact of standards on how the data and information is used once it is interoperable. We see many occasions where data and information moves between settings of care, but it is not used in the medical

decision-making process. A gap may be defined around the quality of the data as well as the process to best incorporate this into the clinical and operational workflows.

Not directly related to gaps, but should be noted, is that measurement tools and methods should not create unintended barriers and / or limitations in relation to existing and new standards.

5. Are the appropriate stakeholders identified who can support collection of needed data? If not, who should be added?

The stakeholders identified are either part of the development lifecycle or embedded in the transaction and data exchange processes. The EHR developers may be able to determine which standards are associated with their applications; however, the HIEs/HIOs/Exchange networks may not be able to determine what standards were used to create and/or transact the data since they only may be able to see the result of the transaction creation and transmission.

Healthcare organization will find themselves dependent upon the ability of their installed EHR technology to collect and measure standard use, transaction volumes, etc.

There may be a need to expand the group to include stakeholders from newer and developing delivery models (i.e. telehealth, mobile technologies) and the post-acute settings for care for example. Also, consideration must be given to how standards might apply to the quality and content of the data which is required for the precision medicine initiatives as well as in the analytics when utilized in the advanced payment models (i.e. ACOs, etc.)

6. Would health IT developers, exchange networks, or other organizations who are data holders be able to monitor the implementation and use of measures outlined in the report? If not, what challenges might they face in developing and reporting on these measures?

As mentioned in the response to Question #5; it is doubtful that the EHRs in use have the capability to monitor the use of standards, other than what is included for use as part of the CEHRT requirements. However, many of the exchange networks can monitor traffic depending upon which transactions sets and methods are in use.

A primary challenge will be the standardization and normalization of the data definitions that will be required for the measures. For the work of gathering or capturing the measures to be meaningful, the gathering and reporting methods need to be the same in all settings.

Please note that the act of gathering and reporting will be a manual and potentially costly endeavor until such time that the automated methods can be designed into the EHR application systems and exchange networks. Again, many providers may opt out of participating due to the barriers of cost and manpower resource requirements needed to support this effort.

7. Ideally, the implementation and use of interoperability standards could be reported on an annual basis to inform the Interoperability Standards Advisory (ISA), which publishes a reference edition annually. Is reporting on the implementation and/or use of interoperability standards on an annual basis feasible? If not, what potential challenges exist to reporting annually? What would be a more viable frequency of measurement given these considerations?

As mentioned in earlier responses, this is something most likely not currently performed and/or considered as part of the operational execution of an HIE/HIO/Exchange Network/Healthcare organizations. Additional feature and functionality would have to be added to the existing transaction solutions, which may in turn require additional staffing to monitor/gather/report. Also, these additional features and functionality most likely will increase costs of software products and platforms.

The cadence of the reporting cycle may be best associated with the lifecycle of the standards updates and/or or certification criteria which may be annually or biennially. This will require consideration for inclusion in current reporting processes for the effort to be meaningful.

8. Given that it will likely not be possible to apply the measurement framework to all available standards, what processes should be put in place to determine the standards that should be monitored?

With the intent of standards and the measurement of standard use having a direct impact on the outcome of care and care quality, one recommendation is to consider which standards would bring the most benefit to the care processes or where standards are best applied in the prevention of errors. Having said that, one might also consider identifying standards categorized by care setting and sector (i.e. patient treatment, transition of care, research, population health, clinical studies, etc.) and ask the stakeholders within the sectors to rank them in importance. The second method may be the most labor and time intensive.

9. How should ONC work with data holders to collaborate on the measures and address such questions as: How will standards be selected for measurement? How will measures be specified so that there is a common definition used by all data holders for consistent reporting?

SHIEC would recommend a public-private collaboration with ONC serving as the convener and organizer of these efforts. Using the process of categorizing the standards would identify stakeholder groups, organized around functional areas, which would identify and prioritize how the standards would be selected for measurement.

SHIEC is a resource that ONC can leverage to support the work in addressing standards utilization and corresponding measurements. SHIEC members are considered an unbiased, trusted data partner in their community who provides information exchange services for clinical, behavioral, social determinants and claims data through longitudinal patient records. Currently, SHIE members are servicing over sixty – four percent (64%) of the total U.S. population with their trusted and well-established information exchange connections. This makes SHIEC a natural partner for ONC to work with in this important effort.

10. What measures should be used to track the level of "conformance" with or customization of standards after implementation in the field?

The use of validation tool sets would be one method to measure both conformance to the standard and identify customization. The availability of such toolset is limited and potentially would need to be developed for the variety of the standards that would be under consideration.

Once again, thank you for your commitment and support with the wide spread adoption, implementation and use of interoperable systems and data exchange which will only facilitate widespread improvement of the healthcare delivery system and achievement of quality patient care outcomes.

Sincerely,

Charles E. Christian

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